UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/674,553	09/30/2003	Erik J. van der Burg	3791	5764

21834 7590 12/24/2008

BECK AND TYSVER P.L.L.C.
2900 THOMAS AVENUE SOUTH
SUITE 100
MINNEAPOLIS, MN 55416

EXAMINER	
HORNBERGER, JENNIFER LEA	
ART UNIT	PAPER NUMBER
3734	

MAIL DATE	DELIVERY MODE
12/24/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/674,553	VAN DER BURG ET AL.	
	Examiner	Art Unit	
	JENNIFER L. HORNBERGER	3734	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 October 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5,38-43,45-50,55-64,66-71,85-91 and 120-180* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5, 38-43, 45-50, 55-64, 66-71, 85-91, and 120-180* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/21/2008 has been entered.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. Claims 1-3, 5, 85-90, 120-125, 128-131, 134, 136-138, 140-142, 145-151, 153-156, 158-160, 164-169, 161-163, and 170-180 are rejected under 35 U.S.C. 102(e) as being anticipated by Whayne et al. (US 5,865,791).

Regarding claim 1-3 and 5, Whayne et al. disclose a method of preventing passage of embolic material from a left atrial appendage of a patient, comprising: providing a deployment catheter having an elongate flexible body with a proximal end and a distal end (Fig. 29; col. 12, ln. 10-11), and an implantable device (95) removably carried by the distal end, said device comprising a barrier, said device radially expandable from a reduced diameter to an enlarged diameter and configured to conform to an inside surface of the left atrial appendage in the sense that the self expanding frame (95) expands to fill the atrial appendage pouch, contacting and

conforming to the inside surface of the pouch (col. 12, ln. 56-61); positioning at least a portion of the device by passing the device into the ostium of the left atrial appendage in the left atrial appendage; and enlarging the device within the left atrial appendage, wherein said barrier extends across the left atrial appendage when enlarged so that the device circumferentially seals against the inside surface of the left atrial appendage. The self-expandable mesh frame (95) is considered to be in circumferential sealing contact with the tissue surface adjacent the opening of the atrial appendage since it expands to fill the atrial appendage pouch and further seals the appendage from thrombus movement.

Regarding claims 85-90 and 180, Whayne et al. disclose a method of performing a procedure at an atrial appendage of a patient, comprising: collapsing an implantable structure (95) to a reduced configuration inside a catheter (col. 12, ln. 10-11; Fig. 29); enlarging the implantable structure inside the atrial appendage adjacent an opening of the atrial appendage; and placing the implantable structure in circumferential sealing contact with a tissue surface adjacent the opening of the atrial appendage (col. 12, ln. 56-61). The expandable mesh frame (95) is considered to be in circumferential sealing contact with the tissue surface adjacent the opening of the atrial appendage since it expands to fill the atrial appendage pouch and further seals the appendage from thrombus movement.

Regarding claims 120-125, 128-131, and 179, Whayne et al. disclose a method of preventing passage of embolic material from a left atrial appendage of a patient, comprising: advancing a catheter having a proximal end and a distal end through the patient until the distal end is disposed adjacent the opening of the patient's left atrial appendage (col. 4, ln. 61 - col. 5, ln.39); releasing an implantable device (95) from the distal end of the catheter to by axially moving the device out of the inner lumen of the catheter to deploy the device (col. 12, ln. 10-11; Fig. 29); the implantable device (95) comprising an expandable frame having a proximal end, a

distal end, a longitudinal axis extending from the proximal end of the distal end, and a barrier, the implantable device having a collapsed configuration and an expanded configuration; positioning the implantable device in the left atrial appendage by inserting it into the left atrial appendage while the device is in its collapsed configuration (col. 12, ln. 56-61); and enlarging the implantable device in the left atrial appendage, wherein the barrier extends across the longitudinal axis when the implantable device is enlarged (col. 12, ln. 56-61), wherein the implantable device is at least a partially self-expanding, and is restrained from expansion until positioned in the left atrial appendage, and wherein said device (95) seals off the left atrial appendage when expanded in the sense that it prevents thrombus movement from the pouch (col. 12, ln. 56-61).

Regarding claims 134 and136-138, Whayne et al. disclose a method of preventing passage of embolic material from a left atrial appendage of a patient, comprising percutaneously delivering and positioning a device (95), comprising an expandable frame, in the left atrial appendage and securing the device relative to the left atrial appendage, the device configured to prevent passage of emboli from the left atrial appendage, wherein the device conforms to an inside wall of the left atrial appendage when positioned therein in the sense that the self expanding frame (95) expands to fill the atrial appendage pouch, contacting and conforming to the inside surface of the pouch (col. 12, ln. 56-61).

Regarding claims 140-142, Whayne et al. disclose a method of preventing passage of embolic material from a left atrial appendage of a patient, comprising: percutaneously and transvascularly delivering an implantable device (95) to the left atrial appendage (col. 4, ln. 61 - col. 5, ln.39); securing the implantable device relative to the left atrial appendage; and preventing passage of embolic material from the left atrial appendage with the implantable device, wherein said preventing passage of embolic material comprises providing a barrier

carried by the implantable device across the interior ostium of left atrial appendage (col. 12, ln. 33-61).

Regarding claims 145-151, Whayne et al. disclose a method of performing a procedure at an atrial appendage of patient, comprising: positioning an implantable structure (95) adjacent the opening of the atrial appendage, the structure having a reduced configuration and an enlarged configuration, wherein the structure is in a reduced configuration while being positioned and is in an enlarged configuration during placement in the atrial appendage, wherein altering the configuration comprises releasing the implantable structure (95) from a delivery device (Fig. 29, col. 12, ln. 10-11) to initially position the structure at the atrial appendage, and wherein the structure conforms to an inner wall tissue surface when enlarged in the sense that the self expanding frame (95) expands to fill the atrial appendage pouch, contacting and conforming to the inside surface of the pouch, to prevent the passage of embolic material from the atrial appendage (col. 12, ln. 56-61).

Regarding claims 153-156, Whayne et al. disclose a method of performing a procedure at an atrial appendage of patient, comprising: providing an implantable structure (95) positioned adjacent the opening of the atrial appendage, the structure having a reduced configuration and an enlarged configuration the enlarged configuration blocking the opening of the atrial appendage; and changing to the enlarged configuration of the structure inside the atrial appendage to prevent passage of embolic material from the atrial appendage (col. 12, ln. 33-60).

Regarding claims 158-160 and 164-169, Whayne et al. disclose a method of performing a procedure at an atrial appendage of a patient, comprising: deploying an implantable structure (95) at the atrial appendage with a catheter (Fig. 29; col. 12, ln.10-11) positioned at the atrial appendage, wherein the catheter is delivered percutaneously (col. 4, ln. 61 - col. 5, ln.39), the

structure (95) placed inside the atrial appendage and being configured to block an opening of the atrial appendage (col. 12, ln. 56-61); and removing the delivery device from its position at the atrial appendage after deploying the implantable structure.

Regarding claims 161-163, Whayne et al. disclose the method further comprising changing the implantable structure from an reduced configuration to an enlarged configuration at the atrial appendage (col. 12, ln. 56-61).

Regarding claims 170-178, Whayne et al. disclose a method of preventing passage of embolic material from an atrial appendage, the method of comprising: delivering a device (95), comprising a generally cylindrical self-expanding frame, to the atrial appendage; and positioning the device into the atrial appendage through the normal opening (col. 12, ln. 56-57), the device when positioned having at least a portion that generally conforms to an inside surface of the atrial appendage in the sense that the self expanding frame (95) expands to fill the atrial appendage pouch, contacting and conforming to the inside surface of the pouch; and wherein embolic material is prevented from passage from the atrial appendage substantially entirely by positioning of the device at the atrial appendage (col. 12, ln. 56-61).

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claim 4, 38-50, 55-61, 63, 64, 66-71, 91, 126, 127, 132, 133, 135, 139, 143, 144, 152, and 157 are rejected under 35 U.S.C. 103(a) as being unpatentable over Whayne et al. (US 5,865,791) in view of Kavteladze et al. (US 5,683,411).

Regarding claims 38, 46-49 and 56-59, Whayne et al. disclose a method of preventing passage of embolic material from a left atrial appendage of a patient, comprising: percutaneously delivering a barrier (95) to the left atrial appendage with a catheter (Fig. 29, col. 12, ln. 10-11 and col. 4 , ln. 61 - col. 5, ln. 39) and positioning the barrier (95) within the atrial appendage adjacent an interior opening of the left atrial appendage (col. 12, ln. 33-61), wherein the barrier comprises an expandable frame (95). Whayne et al. fail to disclose barrier (95) having an at least one anchoring element and engaging the at least one anchoring element with tissue within the interior surface of the left atrial appendage, the at least one anchoring element being operatively connected to the barrier to hold the barrier adjacent the opening and prevent passage of embolic material from the left atrial appendage. Kavteladze et al. disclose a expandable occlusion device (Fig. 3) having anchoring members (17) for ensuring reliable permanent fixing of the occlusion device (col. 5, ln. 33-37). It would have been obvious to one of ordinary skill in the art to provide a plurality of anchoring members to the expandable barrier (95) of Whayne et al. to engage the tissue along the side walls and distal end of the atrial appendage in order maintain the position of the barrier within the atrial appendage as suggested by Kavteladze et al.

Regarding claims 4, 39, 40, 42, 43, 45, 60, 61, 63, 126, 132, 135, and 143, Whayne et al. fails to disclose the expandable frame (95) comprises a mesh. Kavteladze et al. disclose an expandable frame (Fig. 3) comprising a porous film or "mesh" or expanded polytetrafluoroethylene, having a general disc shape, to provide a blood impermeable membrane (col. 5, ln. 30-32). It would have been obvious to one of ordinary skill in the art to modify the expandable frame (95) to include a barrier comprising a porous film or ePTFE member to provide enhanced sealing to the atrial appendage to further prevent thrombus movement from the appendage.

Regarding claim 41, Whayne et al. in view of Kavteladze et al. fail to disclose the pore size of up to about 0.04 inches. It would have been obvious to one having ordinary skill in the art at the time the invention was made to determine the optimum pore size for preventing thrombus movement, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

Regarding claims 50, 55, 64, 91, 127, 133, 139, 144, 152, 157, Whayne et al. in view of Kavteladze et al. disclose the device comprises a porous membrane, but fail to disclose the membrane partially blocks passage of embolic mateiral by supporting tissue growth. However, it is well known that porous mesh materials support tissue growth. It would have been obvious to one of ordinary skill in the art that the mesh should support tissue growth because it would be advantageous to promote the closure of the atrial appendage for further blocking the passage of embolic material.

Regarding claims 66-71, Whayne et al disclose the method further comprising, prior to positioning said device: delivering a trans-septal catheter into the right atrium; advancing a distal tip of the trans-septal catheter through a desired portion of the septum and to the left atrial appendage, wherein the trans-septal catheter curves to direct the distal tip of the trans-septal catheter toward the left atrial appendage; and delivering said device in a delivery catheter through the trans-septal catheter and deploying the device at the left atrial appendage by applying an axial force through a plunger (Fig. 29) slidably received within the catheter to deploy the device from the delivery catheter and causing expansion of the device, wherein a distal end of the delivery catheter is disposed within an opening of the left atrial appendage (Fig. 29, col. 12, ln. 10-11 and col. 4 , ln. 61 - col. 5, ln. 39), and the device being configured to prevent passage of embolic material from the left atrial appendage (col. 12, ln. 56-61).

Response to Arguments

6. Applicant's arguments filed 10/21/2008 have been fully considered but they are not persuasive. Applicant argues that the mesh of Whayne is not placed in the interior of the atrial appendage. Applicant points to the embodiment wherein the mesh is placed over the outside of the inverted atrial appendage. However, in another procedure discussed in col. 12, lines 33-61, Whayne et al. discloses the expandable frame mesh (95) is placed within the interior of the atrial appendage. Further in this discussion, specifically lines 56-61, Whayne et al. discloses the placement of the mesh within the interior of the appendage prevents thrombus movement from the pouch into the atrium.

7. Applicant's arguments with respect to claims 1-5, 38-50, 55-61, 63,64, 66-71, 85-91, 179, and 180 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JENNIFER L. HORNBERGER whose telephone number is (571)270-3642. The examiner can normally be reached on Monday through Friday from 8am-5pm, Eastern time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on (571)272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

jlh
12/19/2008

/Todd E Manahan/
Supervisory Patent Examiner, Art Unit 3731